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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/788,747

02/26/2004

Kenneth W. Carpenter

MEDIV2020-2

8116

28213 7590 05/20/2009

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EXAMINER

HELM, CARALYNNE E

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

05/20/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/788,747	<b>Applicant(s)</b> CARPENTER ET AL.	
	<b>Examiner</b> CARALYNNE HELM	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) 7-9, 16, 20-33, and 35-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 10, 11, 15, 17-19 and 34 is/are rejected.
- 7) ☒ Claim(s) 12-14 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

To summarize the current election, applicant elected of Group I and the species where aminoxyls are the bioactive agent and a polypeptide of 2 to about 25 amino acids is the linker.

### ***Terminal Disclaimer***

The terminal disclaimers filed on 16 March 2009 disclaiming the terminal portion of any patent granted on this application which would extend beyond the of U.S. application numbers 11/098891, 11/345815, 11/128903, 11/147994 have been reviewed and are approved. The terminal disclaimers have been recorded.

### ***Claim Objections***

Claims 12-14 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form. With the new limitations added to claim 1, claims 12-14 redefine the polymer as something all together different than that stated in claim 1. Therefore these claims do not further limit their parent claim.

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Claim 1 is objected to because of the following informalities: the claim recites that the structure depicted is "formula IV"; however the specification states that "formula IV" corresponds to a very different structure (see page 20). The structure depicted in the claim corresponds to formula/structure VI as described by the specification (see page 21). In addition, the definition of R<sub>3</sub> states that it is independently selected from (C<sub>1</sub>-C<sub>6</sub>)alkyl as well as (C<sub>2</sub>-C<sub>6</sub>)alkyl, which is redundant. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of *Graham v. John Deere Co.* have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

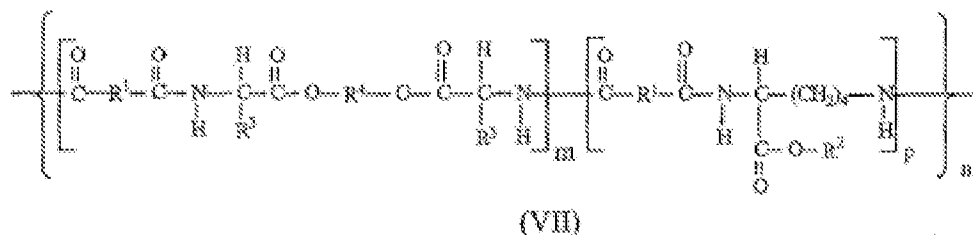
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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6, 10-11, 15, 17-19, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al. (previously cited) in view of Lang et al. (US Patent No. 6,830,747).

Chu et al. teach a drug (bioactive agent) containing biodegradable polymer coating (see page 2 lines 21-26 and 12 lines 3-13; instant claim 1). These drugs are taught to be connected to the polymer via a linker such that upon degradation, the active drug is released (see page 42 lines 1-3; instant claim 2). The polymers of their invention are taught as being applied to the surface of a medical device, where a vascular stent is particularly envisioned (see page 43 lines 1-3 and 9-12; instant claims 1 and 34). A particular set of polymers depicted by formula VII are shown below:

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wherein

$m$  is about 0.1 to about 0.9;

$p$  is about 0.9 to about 0.1;

$n$  is about 50 to about 150;

each  $R^1$  is independently  $(C_2-C_{20})$ alkylene;

each  $R^2$  is independently hydrogen, or  $(C_6-C_{10})$ aryl $(C_1-C_6)$ alkyl;

each  $R^3$  is independently hydrogen,  $(C_1-C_6)$ alkyl,  $(C_2-C_6)$ alkenyl,  $(C_2-C_6)$ alkynyl, or  $(C_6-C_{10})$ aryl $(C_1-C_6)$ alkyl; and

each  $R^4$  is independently  $(C_2-C_{20})$ alkylene.

(see instant claim 1). Chu et al. go on to teach drugs attached to the polymer chain via a linker. The linker is taught to separate the drug from the polymer by 5 angstroms to 200 angstroms and be composed of 2 to about 25 amino acids (see page 39 lines 4-7 and 11-13; instant claims 15, 17, and 19). Such a polypeptide chain is envisioned as poly-L-lysine, poly-L- glutamic acid, poly-L-aspartic acid, poly-L-histidine, poly-L-ornithine, poly-L-threonine, poly-L-tyrosine, poly-L-leucine, poly-L-lysine-L-phenylalanine, poly-L-arginine, or poly-L- lysine-L-tyrosine (see page 40 lines 16-22; instant claim 18). A variety of drugs are taught where the aminoxyl, 4-amino-2, 2, 6, 6,-tetramethylpiperidinyloxy, is exemplified (see example 25; instant claims 3-6 and 10-11). In light of the combined teachings of Chu et al., it would have been obvious to one of ordinary skill at the time of the invention to select a polymer of formula VII with the

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aminoxyl, 4-amino-2, 2, 6, 6,-tetramethylpiperidinyloxy attached via a polypeptide linker of 2 to 25 amino acids in length as the coating on an intravascular stent.

Therefore claims 1-6, 10-11, 15, 17-19, and 34

### ***Response to Arguments***

Applicant's arguments filed March 16, 2009 have been fully considered but they are not persuasive.

Applicant argues that the incorporation by reference of US Patent No. 6,503,538 affects its use as prior art. An incorporation by reference of a patent does not preclude is from use as a prior art reference. Clearly if the patent was incorporated by reference into the disclosure as filed, it was publicly available prior to the filing of the application. In addition, US Patent No. 6,503,538 was not relied upon as prior art in the previous Office action.

### ***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Thursday 8-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/  
Examiner, Art Unit 1615

/MP WOODWARD/  
Supervisory Patent Examiner, Art Unit 1615